



Pesticide Registration Service Fees

PRIA Workshop March 11, 2004



Pesticide Registration Service Fees

- Development of An RD Work Plan Under the Pesticide Registration Improvement Act (PRIA) -

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Stakeholder Questions

- Many questions provided to the Agency relating to development of a new RD work plan under PRIA
- Purpose of this presentation
 - Begin to answer these questions

Stakeholder Questions

- Types of questions
 - How will EPA handle actions currently on the RD FY '04 work plan?
 - How will the Agency handle other pending actions submitted prior to 3/23/04?
 - Will registrants have to pay for pending actions to be worked on?
 - How will actions that are nearly complete be handled?

Stakeholder Questions

- How will priorities be determined between actions that have fees required and ones that do not?
- How will Agency priorities beyond reduced risk compounds (OP alternatives, methyl bromide alternatives) be handled?
- Would paying a fee before the effective date of the fee system allow you to move forward in the queue?

Developing the Schedule

- Two parts to consider in developing the schedule
 - The Actions
 - Received on or after March 23, 2004
 - In-house before March 23, 2004
 - Resources
 - Continuing analysis as funds increase and efficiencies are developed

Actions Received On Or After March 23, 2004

- Actions Covered by Fees
 - Subject to the time frames mandated by the PRIA
 - They will be added to the work plan as they are received with completion dates determined according to the time frames stated in the PRIA

Actions Received On Or After March 23, 2004

- Actions not covered by fees will also need to be scheduled, e.g.:
 - Section 18's
 - Section 24c's
 - EPA initiated amendments
 - Notifications

Actions Received On Or After March 23, 2004

- Time frames for some of these actions are addressed by existing statutory requirements or policy guidelines
- Most IR-4 actions have provisions for fee waivers, but are still subject to the time frames mandated by the PRIA

Actions In-house Prior to March 23, 2004

- Requirements for fees and scheduling for actions in-house before 3/23/04 are not as straight-forward
- PRIA provides some direction
- PRIA allows for some discretion on the part of the Agency and registrants
- Thus, there are decisions that registrants and the Agency need to make

Actions In-house Prior to March 23, 2004

- The chart on the following slide summarizes the direction provided by the PRIA concerning fees and time frames (start dates) for actions in-house prior to March 23, 2004

Actions In-house Prior to March 23, 2004 (cont.)

Summary of Direction Provided in PRIA on Fee Requirements and Review Times (Start Dates) for Pending Actions

Action	Fee Required	Start Date*
New Active Ingredients		
On FY03 RD Workplan	Not Required	30 days after effective date
On FY04 RD Workplan	Required	Not specified in statute
Not on an RD Workplan	Required	Not specified in statute
New Uses and Import Tolerances		
On FY03 RD Workplan	Voluntary	30 days after effective date
On FY04 RD Workplan	Voluntary	If voluntary fee paid, begins on date fee payment is certified
Not on an RD Workplan	Voluntary	
Other Covered Actions		
All other covered pending actions	Voluntary	If voluntary fee paid, begins on date fee payment is certified

*If waiver requested and **granted**, start date is earlier of:

- The date request is granted
- 60 days after receipt of waiver request

*If waiver requested and **denied**, start date is:

- The date of receipt of payment

Actions In-house Prior to March 23, 2004 (cont.)

- The PRIA also directs, for actions in-house prior to March 23, 2004:
 - Fees will be reduced by the amount of previously paid tolerance petition fees
 - The Agency has discretion to prorate the fees based on the amount of work completed on a particular action prior to 3/23/04
 - It is the Agency's intention to prorate these fees

Actions In-house Prior to March 23, 2004 (cont.)

- This is the direction provided by the PRIA on time frames and fees for pending actions
- However, the Agency is mindful of its previous commitments (for which work has begun and is continuing)

Work During the Transition

- Work is continuing on currently scheduled actions (RD '04 work plan; including RD '03 carryovers)
- Currently collecting/verifying the information necessary to analyze workload and develop a new schedule
- Early communication from stakeholders on their plans for in-house actions as well as new actions is crucial

What We Need to Know From Stakeholders

- In-house actions on RD '04 work plan (except new A.I.s)
 - Are you planning to pay the voluntary fee?
- In-house actions not on the work plan
 - Are you still interested in pursuing the action?
 - Are you planning to pay the voluntary fee?
- Later slides will discuss the specific information needed and the procedures for providing this information

How The Agency Will Use The Information

- Developing several “buckets” of actions
 - RD '03 carryovers
 - RD '04 work plan
 - In-house before 3/23 but not on work plan
- Will be further sorted by type of action
 - New A.I. or other use

How The Agency Will Use The Information

- Will be further sorted by
 - If not covered by fee
 - If subject to voluntary fee
- If subject to a voluntary fee will be further sorted by
 - Whether fee is paid or not
- Actions for which a waiver is requested and granted will be considered the same as identical actions for which there is no waiver and for which the voluntary fee is paid

Developing The RD Work Plan

- Proposing a new dynamic schedule will depend on the concrete analysis of the workloads associated with the following
 - Paid/waived fees
 - Actions not covered by fees
 - Work remaining on actions already begun
 - Stakeholder interest in actions in-house for which no work has begun
- This analysis is continuing

How to Provide Information/ Payment for Pending Actions

- IN ALL CASES
 - Do not send any payment until you receive a bill from the Agency!

How to Provide Information/ Payment for Pending Actions

- New A.I.s Carried Over From RD FY'03 Work Plan on RD FY'04 Work Plan
 - Do Nothing (no fee required)
- All Other New A.I.s In-house
 - The Agency will automatically send bills for the required fee
 - Reduced by amount of previously paid tolerance petition fees and prorated based on work already completed
 - Will include instructions on how to pay (or how to submit a waiver request)
- All Other Actions (covered by voluntary fees)
 - You Should Initiate Contact With the Agency

How to Provide Information/ Payment for Pending Actions

- Actions In-House Before 3/23/04
(Covered by Voluntary Fees)
 - Submit New Application Form or Letter Which Contains the Following Information (if using application form, check “Other” box at the top of the form):
 - Provide Previously Assigned Reg.#/Petition #/OPP Identifier #
 - Provide Date of Original Application
 - Provide e-mail address &/or Fax #
 - State That You Are Still Interested in Pursuing the Application

How to Provide Information/ Payment for Pending Actions

- State Whether You Intend Pay the Voluntary Fee
- If You Intend to Pay the Voluntary Fee
 - Identify Proposed Fee Category and Fee for That Category
- If Requesting a Waiver
 - Include Request and Documentation
- Mail or Courier to Document Processing Desk (same as for new applications)
- Identify by the Distribution Code (VOLPAY)

How to Provide Information/ Payment for Pending Actions

- The Agency Will:
 - For Applicants Who Choose to Pay Voluntary Fee (including those who request a waiver)
 - Determine appropriate fee category
 - Reduce fee by amount of any previously paid tolerance petition fees; prorate based on work already completed; and reduce by the amount of any waiver granted
 - Mail and E-mail or Fax letter/invoice that includes amount due and instructions for submitting payment

Summary

- Appreciate your thoughtful consideration and raising of these issues
- It is extremely useful to look at many related questions together and up-front
- Look forward to your continued input
- Will continue to consult stakeholders on proposed schedule

Inert Ingredients in the Pesticide Registration Improvement Act

- No provision for direct fees for inert ingredient actions
- Additional resources provided

Inert Ingredients in the PRIA

- Two provisions under PRIA for inert ingredient resources:
 - Pesticide Registration Fees
 - Maintenance Fees

Inert Ingredient Actions Covered under PRIA

- Petitions submitted for the establishment of a tolerance or a tolerance exemption
- Actions pending as of March 23, 2004 or submitted subsequently

Inert Ingredient Activities Covered under PRIA

- In-processing of inert ingredient submissions
- Review of submitted data on new inert ingredients
- Risk assessments performed on new inert ingredients
- Establishment of new inert ingredient tolerances/tolerance exemptions
- Other associated product registration determinations involving new inert ingredients
- There are currently 50 inert ingredient tolerance/tolerance exemption petitions pending review

Inert Review Process Improvements

- Accelerating the new inert review process
- Workplans being developed for new inert ingredients
- Refining review methodology